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10/576,991

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EXAMINER

PIHONAK, SARAH

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/576,991	<b>Applicant(s)</b> RAUL ET AL.	
	<b>Examiner</b> SARAH PIHONAK	<b>Art Unit</b> 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 8, 13 and 19-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/10/2010, 3/26/2010</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This application is a 371 (national stage application) of PCT/US04/35619, filed on 10/27/2004.

### **Priority**

This application claims priority to Provisional Application No. 60/514709, filed on 10/27/2003.

### **Response to Remarks**

1. Applicant's arguments filed 2/11/2010, regarding the rejection of claims 1-7, 9-12, and 14-17 under 35 USC 103(a) have been fully considered but they are not persuasive. Applicants have argued that the claims are not obvious over Kosal et. al., in view of Ulrich et. al., because Kosal et. al. teaches an oil-in-water emulsion comprised of a pressure sensitive adhesive, a surfactant, and a thickening agent; the pressure sensitive adhesive is a product of a crosslinking reaction between a hydroxyl terminated polydiorganosiloxane such as hydroxy terminated polydimethylsiloxane, and a silanol containing silicone resin, in which the components are dispersed in a volatile silicon fluid. The Applicants maintain that as the instantly claimed emulsion is substantially free of lipophilic solvent, and as Kosal teaches the presence of a volatile silicon fluid, the claims are not obvious. The examiner respectfully disagrees. Kosal. teaches a volatile silicon fluid; while it is acknowledged that some silicone fluids are lipophilic, there are others that are non-lipophilic. Kosal broadly teaches the presence of a silicone fluid;

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therefore, as there are silicone fluids which are non-lipophilic, Kosal still renders the claimed invention obvious, as Kosal teaches the claimed oil-in-water emulsion comprised the elected silicone component, a surfactant, and water. As the claimed composition contains comprising language, it does not exclude the presence of non-lipophilic silicone fluids.

2. The Applicants have also argued that it was not addressed that the claimed oil-in-water emulsion is substantially free of lipophilic solvent and is formed by mechanical inversion of a water-in-oil emulsion. As discussed supra, Kosal broadly teaches the presence of silicone fluids, of which there are non-lipophilic species, in addition to lipophilic species. Regarding the language drawn to the 'mechanical inversion of a water-in-oil emulsion', it is noted that the claims are drawn to a composition, and are therefore a product-by-process claims. The claims are examined as a product, and determination of patentability is not made based upon language drawn to the process. Furthermore, Kosal teaches an inversion process for the preparation of the emulsion, with references to mechanical mixing (column 5, lines 4-13; column 6, lines 30-48). Therefore, as Kosal teaches the claimed oil-in-water emulsion comprised the elected silicone component, a surfactant, and water, the claimed composition is obvious over Kosal. The Applicants have stated that supplemental solvents are not used in the present invention; however, it is noted that the claims cite "substantially free of lipophilic solvent", which therefore excludes only lipophilic solvents, and not all solvents. The claims contain comprising language, which does not exclude the presence of non-lipophilic solvents or fluids.

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3. In the office action dated 11/13/2009, claim 18 was withdrawn, as it was drawn to a method, and not the elected invention of a composition. In the reply filed on 2/10/2010, claim 18 was amended to be drawn to a composition, dependent upon claim 1. Therefore, this claim was examined along with claims 1-7, 9-12, and 14-17 in this office action. Claims 8, 13, and 19-41 were withdrawn due to the restriction requirement. A modified rejection under 35 USC 103(a) has been made, as necessary to address the claim limitations of amended claim 18. Accordingly, this action is made FINAL. The claims were examined with regards to the previously elected species of the following: for the silicone component, the reaction product of a hydroxyl endblocked polydimethylsiloxane polymer and a hydroxyl functional silicate resin (trimethylsiloxy and hydroxyl endblocked silicate resin); triethanolamine linear alkylate sulfonate for the surfactant; polyvinyl alcohol as the thickening agent; and ketoconazole as the active drug.

4. Claims 1-7, 9-12, and 14-18 were examined.

5. Claims 1-7, 9-12, and 14-18 are rejected.

### **Claim Rejections-35 USC § 103**

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-7, 9-12, and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosal, US Patent No. 6,545,086, in view of Gray et. al., US Patent No. 6,040,307, and further in view of Ulrich, US Patent No. 6,365,146.

The claims are drawn to a controlled-release composition for topical application comprising an oil-in-water emulsion of a silicone component formed from the reaction of a hydroxyl endblocked polydimethylsiloxane polymer and a hydroxyl functional silicate resin (trimethylsiloxy and hydroxyl endblocked silicate resin); the surfactant triethanolamine linear alkylate sulfonate; an additional silicone-based surfactant as a

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dispersing agent, polyvinyl alcohol as a thickening agent; and the drug ketoconazole.

The claims are also drawn to the silicone component as a pressure sensitive adhesive, and to the active drug being present in a liquid, viscous, powder, or crystalline form.

Kosal teaches an oil-in-water emulsion composition comprised of a pressure sensitive adhesive, a surfactant, and a thickening agent for medical and personal care utility (Abstract; column 1, lines 16-24). The pressure sensitive adhesive is taught as being comprised of a crosslinking reaction between a hydroxyl terminated polydiorganosiloxane such as hydroxy terminated polydimethylsiloxane, and a silanol containing silicone resin (column 2, lines 30-60). It is taught that the silanol containing silicone resin has hydroxyl end groups, as well as trimethyl end groups (column 2, lines 45-60). It is taught that polyvinyl alcohol is used as a thickening agent (column 5, lines 4-13), and that the triethanolamine linear alkylate sulfonate surfactant, known commercially as Bio-Soft N-300 is present in the composition as a surfactant (column 6, Example 1, lines 36-39). Silicone based surfactants, such as those comprised of siloxane polyalkylene copolymers, are taught, as well as combinations of surfactants (column 3, line 66-column 4, line 18). Kosal teaches that the emulsion composition comprised of the pressure sensitive adhesive, polyvinyl alcohol, and triethanolamine linear sulfonate is used in medical applications, such as transdermal drug delivery, and to maintain an active drug, such as a fungicide, to the surface of the skin (column 5, lines 14-30). While Kosal does not explicitly teach that the drug delivery to the skin is in the form of sustained or controlled release, transdermal drug delivery is taught. It is well known in the art that transdermal drug delivery is used to provide a controlled release of

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the desired active agent to the skin of the subject or patient. While Kosal does not explicitly teach that the silicone component and surfactant comprise a homogeneous oil phase, the surfactant, triethanolamine dodecylbenzene sulfonate and the silicone component are mixed together, followed by addition of water to form an oil-in-water emulsion (column 6, lines 30-48); thus, the combination of the silicone component and surfactant comprises the oil phase, which, without evidence to the contrary, would have been expected to be homogeneous. It is taught that the amount of water present in the emulsion ranges from at least 0.5 %, up to 200%, of the total weight of the silicone pressure sensitive adhesive and silicone fluid (column 4, lines 55-65). It is not explicitly taught that the oil-in-water emulsion has solids content from 25 to 85 parts by weight based upon 100 parts by weight of the oil-in-water emulsion. However, Kosal teaches an oil-in-water emulsion composition comprised of a silicone component (formed by reaction of a hydroxyl endblocked polydimethylsiloxane polymer and a hydroxyl functional silicate resin (trimethylsiloxy and hydroxyl terminated silicate resin), polyvinyl alcohol, and the triethanolamine dodecylbenzene sulfonate surfactant, as claimed; thus, it would have been expected that the solids content of the emulsion would have comprised between 25 to 85 parts by weight.

While Kosal teaches a composition comprised of a pressure sensitive adhesive (formed by reaction of a hydroxyl endblocked polydimethylsiloxane polymer and a hydroxyl functional silicate resin (trimethylsiloxy and hydroxyl terminated silicate resin), polyvinyl alcohol, and the triethanolamine dodecylbenzene sulfonate surfactant, or Bio-Soft N-300 is effective as a transdermal drug delivery system or to hold a fungicide to



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the skin of a patient, it is not explicitly taught that the active drug contained in the system is ketoconazole.

Gray et. al. teaches that ketoconazole is a fungicide useful for fungal infections of the skin, as well as systemic infections (Abstract; column 1, lines 15-21). Gray et. al. teaches that ketoconazole can be administered by a variety of routes, including topically (column 6, lines 18-25; lines 61-63). It is also taught that ketoconazole can be administered in a controlled release or controlled delivery manner (column 6, lines 64-67), and administered topically as a solid, semi-solid, solution, powder, or a viscous form (column 7, lines 32-45).

It would have been prima facie obvious for one of ordinary skill in the art, at the time of the invention, to prepare a composition comprised of the pressure sensitive adhesive, surfactant, thickener, and emulsion taught by Kosal and the active agent ketoconazole because Kosal teaches that the pressure sensitive adhesive comprised oil-in-water emulsion is effective for transdermal drug delivery, and for maintaining fungicidal active agents on the surface of skin. As ketoconazole is taught by Gray et. al. as a fungicide for treating local and systemic infections, and can be administered topically and in controlled release formulations, one of ordinary skill in the art would have expected success in utilizing the composition taught by Kosal to deliver ketoconazole in a controlled release manner topically, for drug delivery.

While Kosal does not explicitly teach that the surfactants encapsulate the active agent, Ulrich teaches that surfactants are commonly used for drug delivery, as the micelles formed from the surfactant are able to solubilize hydrophobic drugs, within a

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hydrophilic outer shell (column 1, lines 45-51). Therefore, as it is taught that surfactants are effective for solubilizing hydrophobic drugs, and form a hydrophilic outer shell, it would have been obvious that the surfactants taught by Kosal in effect encapsulate the active agent, ketoconazole.

### **Information Disclosure Statements**

10. The information disclosure statements (IDS) submitted on 2/10/2010 and 3/26/2010 were filed after the mailing date of the non-final action on 11/13/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Conclusion**

12. No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.  
/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1627

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